Remarks

Applicant notes with appreciation that the Office action withdraws rejection of claims 1-21 under 35 U.S.C. §102(e) in view of Keast et al. (U.S. patent number 6,749,606, filed September 4, 2001 and issued June 15, 2004).

Claims 1-21 are pending herein. No new matter has been added, and no new material presented that would necessitate an additional search on the part of the Examiner.

Claims comply with 35 U.S.C. §102(b)

The Office action pp. 2-3 now rejects claims 1-5, 9, 12-13, 15-17, and 21 under 35 U.S.C. §102(b) in view of Rotteveel et al. (U.S. patent number 5,669,389 issued September 23, 1997). Applicant respectfully traverses.

According to criteria established in the Manual of Patent Examining Procedure, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Manual of Patent Examining Procedure* § 2131 (8th ed., Rev. 6, September 2007), *citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987).

Thus, the standard for rejection under 35 U.S.C. §102 is identity.

Rotteveel et al. (U.S. patent number 5,669,389 issued September 23, 1997)

Rotteveel shows an endoscope probe with a probe head having a cavity or circular aperture in which is placed an ultrasonic transducer (Rotteveel et al., Abstract). The probe head of Rotteveel's endoscope is constructed of a holder and a free end that is shut-off by a semicircular wall (Ibid., column 2 lines 58-64). The holder has a circular aperture for placement of the ultrasonic transducer (Ibid., column 2 lines 64-65 and FIG. 2).

The cavity or aperture in the probe head is sealed with an acoustically transparent lens and the transducer is coupled acoustically to a fixed cap (Ibid., Abstract). Rotteveel's states:

> A hard concave acoustic lens **81** which rotates along with the transducer is fitted on the transducer and can be, for example, glued on the transducer. The concave lens can be an acrylic lens or an anamorphotic type of lens made of hard epoxy resin. The lengthwise direction of the cavity corresponds to that of the individual elements of the transducer. The cavity of the lens in the example shown is filled with a so-called flat filler **82** which together with the lens forms a plane-parallel unit. … An ultrasonic sound-transmitting cap **85** is fitted, also in a sealing manner, in the ring **83**. The cap **85** is preferably made of hard material such as methylpentene copolymer silicone rubber, and in the example shown is glued to

> the ring **83**, as indicated schematically at **86**. The ring **83**, which can be made of, e.g. glass ceramic material, lies with the bottom axial plane against the lens **81**. Between the cap and the lens is a <u>chamber</u> **87** which along the periphery is bounded by the ring **83** and which is filled with an <u>electrically non-conducting degassed fluid</u>. [Ibid., column 5 lines 31-57; emphases added].

In contrast to Rotteveel's endoscope, claims 1, 9, and 21 are directed to an apparatus having an endoscope including a distal end; at least one ultrasound transducer contained within the distal end; and an outer protective shell directly covering the distal end and fabricated from an electrically insulating material having a <u>Thermal Conductance greater than 1 W/M-°K</u> overlaying at least a portion of said distal end. Claim 15 is directed to a method of scanning a patient's heart using a TEE probe including providing an endoscope having a distal end having a portion thereof forming an outer protective shell directly covering the distal end fabricated from an electrically insulating material having a <u>Thermal Conductance greater than 1 W/M-°K</u>.

Endoscopic probes used currently in medical examinations are susceptible to overheating, and are often limited by the thermal rise of the probe surface from transducer self-heating during normal operation. Specification as filed, p. 1 lines 24-25. A cause of the overheating phenomenon is due to the <u>inefficient conduction</u> of heat from the transducer to the patient. Specification as filed, p. 2 lines 13-15.

The claims of the present invention address this problem, as the claims are directed to an apparatus and a method including an endoscope having a distal end and an outer protective shell directly covering the distal end that is fabricated from an electrically insulating material having a <u>Thermal Conductance greater than 1 W/M-°K</u>. Nowhere does Rotteveel show an outer protective shell covering the distal end of an endoscope in which the outer protective shell is fabricated from an electrically insulating material having a <u>Thermal Conductance greater than 1 W/M-°K</u>.

Rotteveel states in contrast that the cavity or aperture containing his ultrasonic transducer is sealed by the lens, the flat filler, the sound-transmitting cap, and the chamber filled with an electrically non-conducting degassed fluid (Ibid. column 3 lines 21-24 and column 5 lines 31-57). None of Rotteveel's materials have a <u>Thermal Conductance greater than 1 W/M-°K</u>, as shown below.

Rotteveel fails to provide any example of any electrically non-conducting degassed fluid nor any example of any flat filler. Therefore, nowhere does Rotteveel show that the electrically

non-conducting degassed fluid or the flat filler has a Thermal Conductance of greater than 1 W/M-°K.

Rotteveel's lens is made from an acrylic or a hard epoxy resin (Ibid. column 5 lines 31-35), and the sound-transmitting cap is made from methylpentene copolymer silicone rubber (Ibid. column 5 lines 48-51).

One of ordinary skill in the art of physics or material science would have understood at the time the application was filed that none of acrylic, epoxy, and silicone rubber has a Thermal Conductance of greater than 1 W/M-°K, to which claims 1, 9, 15, and 21 are directed. Attached hereto as evidence is a table showing Thermal Conductance of acrylic and epoxy. See Appendix **A**. This table shows that acrylic has a Thermal Conductance of 0.2 W/M-°K, and that epoxy has a Thermal Conductance of 0.35 W/M-°K.

Further attached hereto as Appendix **B** is a table showing Thermal Conductance of silicone rubber. This table shows that silicone rubber has a Thermal Conductance of 0.002 W/cm-°K. Converting to the same type of unit, i.e., converting centimeters to meters, one readily calculates that silicone rubber has a Thermal Conductance of 0.00002 W/M-°K.

Thus factual analyses above demonstrate that none of the materials used to make up the outer protective shell of Rotteveel's endoscope has a Thermal Conductance of greater than 1 W/M-°K, to which claims 1, 9, 15, and 21 are directed. Therefore Rotteveel is not the same as the subject matter of claims 1, 9, 15, and 21. Because the standard for rejection under 35 U.S.C. §102 is identity, and because Rotteveel is not the same as clams 1, 9, 15, and 21, these claims are novel in view of Rotteveel.

The Office action on p. 3 alleges, "[i]n the broadest interpretation of the claim, the outer protective shell consists of elements 81, 82, and 87 and 85 of Rotteveel et al. and thus is fabricated with elements having an overall thermal conductivity of greater than 1 W/M-°K." Applicant respectfully traverses.

Elements 81, 82, 85, and 87 are identified respectively in Rotteveel as follows: acoustic lens (81). flat filler (82), sound-transmitting cap (85), and chamber (87) that is filled with an electrically non-conducting degassed fluid. Factual analyses above demonstrate that Rotteveel fails to provide any example of any electrically non-conducting degassed fluid nor any example of any flat filler. Therefore, nowhere does Rotteveel show that the electrically non-conducting degassed fluid or the flat filler has a Thermal Conductance of greater than 1 W/M-°K.

Further, neither the lens nor the cap of Rotteveel's endoscope has a Thermal Conductance of greater than 1 W/M-°K, as shown above. Rather, Rotteveel shows that lens (81) is made from an acrylic or a hard epoxy resin, which have Thermal Conductances of 0.2 W/M-°K and 0.35 W/M-°K respectively. Rotteveel shows that the sound transmitting cap (85) is made from methylpentene copolymer silicone rubber, which has a Thermal Conductance of 0.00002 W/M-°K.

Therefore, Rotteveel fails to show any apparatus, device, or method that includes an outer protective shell that is fabricated from an electrically insulating material having a Thermal Conductance greater than 1 W/M-°K, to which claims 1, 9, 15, and 21 are directed.

For these reasons, Rotteveel is not the same as the subject matter of claims 1, 9, 15, and 21, and therefore these claims are novel in view of Rotteveel. Claims 2-5, 9, 12-13, and 16-17 depend directly or indirectly from claims 1, 9, and 15 and incorporate all of the subject matter of these claims and include additional subject matter. Therefore claims 2-5, 9, 12-13, and 16-17 also are novel in view of Rotteveel.

Applicant respectfully requests withdrawal of rejection of claims 1-5, 9, 12-13, 15-17, and 21 under 35 U.S.C. §102(b) in view of Rotteveel.

Claims comply with 35 U.S.C. §103(a)

The Office action on p. 3 rejects claims 6-8, 10-11, 14, and 18-20 in view of the combination of Rotteveel and Yagami et al. (U.S. patent number 5,738,100 issued April 14, 1998). Applicant respectfully traverses.

Rotteveel is characterized above. Applicant shows below that Yagami does not cure the defects of Rotteveel, alone or in any combination. Further, the principles of operation of devices in these references are shown below to have rendered the combination inoperative.

The ultimate determination of whether an invention would have been obvious under 35 U.S.C. §103(a) is a legal conclusion based on underlying findings of fact. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000).

As a preliminary matter, the Supreme Court in *Graham v. John Deere*, 383 U.S. 1 provided an analytical construct to be used when determining whether claims are obvious under 35 U.S.C. §103(a) in view of prior art. One aspect of this analytical construct includes characterizing the prior art, as a background for a legal analysis.

Yagami et al. (U.S. patent number 5,738,100 issued April 14, 1998)

Yagami shows an ultrasonic imaging catheter (Yagami et al., Abstract). In use, an ultrasonic imaging catheter is inserted into a thin vessel such as a coronary artery of a heart or the vas such as a bile duct to obtain a tomogram of the vessel or the vas or to make a measurement of a blood flow therein (Ibid., column 1 lines 6-10). The problem to be solved in Yagami is to make a flexible tip portion of a catheter to improve movement of the catheter within the blood vessel (Ibid., column 1 lines 19-21).

Yagami's ultrasonic imaging catheter is designed to improve movement of the catheter within the blood vessel by placing the housing that holds the ultrasonic transducer in the body of the catheter and adding elastic members to the distal end of the catheter for improved flexibility (Ibid., column 4 lines 6-25 and Fig. 1).

Yagami states that a first elastic member is formed at the free end of the catheter, i.e., at the tip of the outer sheath (Ibid., column 5 lines 26-29 and Fig. 1). The first elastic member protrudes to the tip of the outer sheath (Ibid., column 5 lines 29-30 and Fig. 1). A second elastic member is connected with the tee end of the housing, and the second elastic member extends toward the tip direction of the catheter (Ibid., column 30-32 and Fig. 1). The second elastic member extends up to inside of the first elastic member, i.e., the tip of the second elastic member is positioned within the first elastic member (Ibid., column 5 lines 31-36 and Fig. 1).

Nowhere does Yagami teach or suggest an apparatus having an endoscope including a distal end; at least one ultrasound transducer contained within the distal end; and an outer protective shell directly covering the distal end and fabricated from an electrically insulating material having a Thermal Conductance greater than 1 W/M-°K overlaying at least a portion of said distal end, to which claims 1 and 9 are directed.

In contrast to the subject matter of the present claims, the transducer of Yagami's ultrasonic imaging catheter is located within the body of the outer sheath, and not located within the distal end of the apparatus (Ibid., Fig. 1). Rather, the distal end of Yagami's ultrasonic imaging catheter contains the first and second elastic members (Ibid., Fig. 1).

Yagami fails to teach or suggest a method of scanning a patient's heart using a TEE probe including providing an endoscope having a distal end having a portion thereof forming an outer protective shell directly covering the distal end fabricated from an electrically insulating material having a Thermal Conductance greater than 1 W/M-°K, to which claim 15 is directed.

Therefore claims 1, 9, and 15 are not obvious in view of the combination of Rotteveel and Yagami. Claims 6-8, 10-11, 14, and 18-20 depend directly or indirectly from claims 1, 9, and 15 and incorporate all of the subject matter of these claims and include additional subject matter. Therefore claims 6-8, 10-11, 14, and 18-20 also are not obvious in view of the combination of Rotteveel and Yagami.

Legal analysis of references combined

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *Manual of Patent Examining Procedure*, §2143.01, 8th Ed. Rev. September, 2007 [emphasis in original]. The U.S. Supreme Court in *KSR International Co. v. Teleflex Inc.* 550 U.S.____ (2007), affirmed the legal principle that the mere fact that each element of a claimed invention could be found within the prior art does not render the claimed invention obvious. The court stated:

> .... A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR International Co.* 550 U.S.____ at p. 14

In fact, the court in *KSR* explains "... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the newly claimed invention does." Id. at p.15.

Applicant respectfully traverses the above rejection, and show that the facts of the case and the relevant case law indicate that the invention would not have been obvious to one of ordinary skill in the art at the time the application was filed because the underlying facts show that the criteria for a *prima facie* rejection have not been met.

Lack of motivation to combine the cited prior art

According to criteria established in the M.P.E.P., "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. 2143.01.

Applicant shows below that to have combined Rotteveel and Yagami at the time the present application was filed in an attempt to have arrived at the subject matter of the present claims would have rendered Yagami's ultrasonic imaging catheter unsatisfactory for its intended purpose.

Yagami's ultrasonic imaging catheter is designed to improve movement of the catheter within the blood vessel by placing the housing that holds the ultrasonic transducer in the body of the catheter and adding elastic members to the distal end of the catheter for improved flexibility of that end (Ibid., column 4 lines 6-25 and Fig. 1). Yagami states that a first elastic member is formed at the free end of the catheter, i.e., at the tip of the outer sheath (Ibid., column 5 lines 26-29 and Fig. 1). The second elastic member is connected with the tee end of the housing, and the second elastic member extends toward the tip direction of the catheter (Ibid., column 30-32 and Fig. 1). The second elastic member extends up to inside of the first elastic member, i.e., the tip of the second elastic member is positioned within the first elastic member (Ibid., column 5 lines 31-36 and Fig. 1).

In contrast to Yagami, Rotteveel shows an endoscopic probe, in particular a transesophageal echocardiogram (TEE) probe in which the ultrasonic transducer is contained within the distal end of the probe.

To have combined Rotteveel and Yagami to have arrived at the subject matter of the pending claims would have required moving the ultrasonic transducer from the body of Yagami's catheter into the flexible tip of the catheter. Had the transducer of Yagami's ultrasonic imaging catheter been moved to the tip of the catheter, the tip of Yagami's ultrasonic imaging catheter would have been made rigid, i.e., inflexible. Therefore this modification would have rendered Yagami's technology unsatisfactory for its intended purpose.

Thus moving the ultrasonic transducer from the body of Yagami's catheter into the flexible tip of the catheter to attempt to have arrived at the subject matter of the present claims would have rendered Yagami's ultrasonic imaging catheter unsatisfactory for its intended purpose. Therefore there would have been no motivation to have combined Rotteveel and Yagami.

For this reason also, claims 1, 9, and 15 are not obvious in view of the combination of Rotteveel and Yagami. Claims 6-8, 10-11, 14, and 18-20 depend directly or indirectly from claims 1, 9, and 15 and incorporate all of the subject matter of these claims and include additional subject matter. Therefore claims 6-8, 10-11, 14, and 18-20 also are not obvious in view of the combination of Rotteveel and Yagami.

Applicant respectfully requests withdrawal of rejection of claims 6-8, 10-11, 14, and 18-20 under 35 U.S.C. §103(a) in view of the combination of Rotteveel and Yagami.

<u>Summary</u>

On the basis of the foregoing reasons, Applicant respectfully submits that the pending claims are in condition for allowance, which is respectfully requested.

If there are any questions regarding these remarks, the Examiners are invited and encouraged to contact Applicant's representative at the telephone number provided.

Respectfully submitted,

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Thermal Conductivity of some common Materials

Thermal conductivity of some common materials as aluminum, asphalt, brass, copper, steel and many more

Thermal conductivity is the quantity of heat transmitted through a unit thickness in a direction normal to a surface of unit area, due to a unit temperature gradient under steady state conditions.

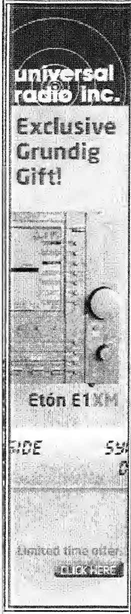
Thermal conductivity, or heat transfer coefficients, of some common materials and products can be found in the table below:

Thermal Conductivity - *k* - (W/m K)			
Material/Substance	Temperature (^oC)		
	25	125	225
Acetone	0.16		
Acrylic	0.2		
Air	0.024		
Alcohol	0.17		
Aluminum	250	255	250
Aluminum Oxide	30		
Ammonia	0.022		
Antimony	18.5		
Argon	0.016		
Asbestos-cement board	0.744		
Asbestos-cement sheets	0.166		
Asbestos-cement	2.07		
Asbestos, loosely packed	0.15		
Asbestos mill board	0.14		
Asphalt	0.75		
Balsa	0.048		
Bitumen	0.17		
Benzene	0.16		
Beryllium	218		
Brass	109		
Brick dense	1.31		
Brick work	0.69		
Cadmium	92		
Carbon	1.7		
Cement, portland	0.29		
Cement, mortar	1.73		
Chalk	0.09		
Cobalt	69		

Concrete, light	0.42		
Concrete, stone	1.7		
Constantan	22		
Copper	401	400	398
Corian (ceramic filled)	1.06		
Corkboard	0.043		
Cork, regranulated	0.044		
Cork, ground	0.043		
Cotton	0.03		
Carbon Steel	54	51	47
Cotton Wool insulation	0.029		
Diatomaceous earth (Sil-o-cel)	0.06		
Earth, dry	1.5		
Ether	0.14		
Epoxy	0.35		
Felt insulation	0.04		
Fiberglass	0.04		
Fiber insulating board	0.048		
Fiber hardboard	0.2		
Fireclay brick 500°C	1.4		
Foam Glass	0.042		
Gasoline	0.15		
Glass	1.05		
Glass, Pearls, dry	0.18		
Glass, Pearls, saturated	0.76		
Class, window	0.96		
Glass, wool Insulation	0.04		
Glycerol	0.28		
Gold	310	312	310
Granite	1.7 - 4.0		
Gypsum or plaster board	0.17		
Hairfelt	0.05		
Hardboard high density	0.15		
Hardwoods (oak, maple..)	0.16		
Helium	0.142		
Hydrogen	0.168		
Ice (0°C, 32°F)	2.18		
Insulation materials	0.035 - 0.16		
Iridium	147		
Iron	80	68	60
Iron, wrought	59		
Iron, cast	55		
Kapok insulation	0.034		
Kerosene	0.15		
Lead Pb	35		
Leather, dry	0.14		
Limestone	1.26 - 1.33		
Magnesia insulation (85%)	0.07		
Magnesium	156		
Marble	2.6		

Thermal Conductivity & Coefficient of Expansiona

Substance	Thermal Conductivity (W/cm·°C)	Coefficient of Thermal Expansion (ppm/°C)	Density (g/cm^3)	Specific Thermal Conductivity[b] (W/cm·°C)
Air (still)	0.0003			
Alumina	0.276			
Alumina (85%)	0.118			
Aluminum	2.165	0.23	2.7	0.81
Beryllia (99.5%)	1.063			
Beryliia (97%)	1.575			
Beryllia (95%)	1.161			
Beryllium	1.772			
Beryllium-Copper	1.063			
Boron Nitride	0.394			
Brass (70/30)	1.220			
Copper	3.937	0.17	8.9	0.45
Copper/Inv[c]/Copper	1.64	0.084	8.4	.020
Copper/Mo[d]/Copper	1.82	0.084	9.9	0.18
Copper/Mo[d]-Cu/Copper	2.45-2.80	0.60-0.10	9.4	0.26-0.30
Diamond (room temp)	6.299			
Epoxy	0.002			
Epoxy (thermally conductive)	0.008			
FR-4 (G-10)	0.003			
GaAs	0.591			
Glass	0.008			
Gold	2.913			
Heatsink Compound	0.004			
Helium (liquid)	0.000307			
Invar	0.11	0.013	8.1	0.014
Iron	0.669			
Kovar	0.17	0.59	8.3	0.020
Lead	0.343			
Magnesium	1.575			
Mica	0.007			
Molybdenum	1.299			
Monel	0.197			



Mylar	0.002			
Nickel	0.906			
Nitrogen (liquid)	0.001411			
Phenolic	0.002			
Platinum	0.734			
Sapphire (a-axis)	0.32			
Sapphire (c-axis)	0.35			
Silicon (pure)	1.457			
Silicon (0.0025 Ω-cm)	1.457			
Silicon Carbide	0.90			
Silicon Dioxide (amorphous)	0.014			
Silicon Dioxide (quartz, a-axis)	0.059			
Silicon Dioxide (quartz, c-axis)	0.11			
Silicone Grease	0.002			
Silicone Rubber	0.002			
Silicon Nitride	0.16 - 0.33			
Silver	4.173			
Stainless Steel (321)	0.146			
Stainless Steel (410)	0.240			
Steel (low carbon)	0.669			
Teflon	0.002			
Tin	0.630			
Titanium	0.219	0.086	4.4	0.016
Tungsten	1.969			
Water	0.0055			
Zinc	1.024			

a: Approximate values from 0 °C to 100 °C
b: Thermal conductivity divided by specific gravity (introduced by Dr. Carl Zweben & K.A. Schmidt)
c: Invar
d: Molybdenum

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